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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 08/560,024      | 02/20/96    | CHEN                 | Y LUD-5354.1-J      |

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NEW YORK NY 10022

18M1/0916

EXAMINER

CAPUTA, A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1817     | 9            |

DATE MAILED: 09/16/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.  
**08/560,024**

Applicant(s)

Chen et al.

Examiner

Anthony C. Caputa

Group Art Unit

1817



Responsive to communication(s) filed on Jun 16, 1997.

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

Claim(s) 8-20 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) 11, 12, 15, and 16 is/are allowed.

Claim(s) 8-10, 13, 14, and 17-20 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 4.5

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1817

### **DETAILED ACTION**

1. The prior objection to disclosure is withdrawn in view of applicants' amendment.
2. The Examiner acknowledges that Applicants sent a copy of the WO 92/20356 reference in the IDS received 3/20/96 (see Paper No. 4.5). Accordingly, the WO 92/20356 reference not considered in the previous Office Action is considered. The Examiner notes that the second reference by Boon et al was considered.
3. The following is a quotation of the first paragraph of 35 U.S.C. § 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. The prior objection to the specification under 35 U.S.C. § 112, first paragraph for failing to provide an enabling disclosure is maintained for the reasons as set forth in the last Office Action.

Applicants essentially argue the rejection should be withdrawn since the references cited by the Examiner (e.g. Lazar et al., and Burgess et al.) are drawn to a growth factor and not a tumor rejection antigen precursor. Applicants arguments are not persuasive to obviate the rejection. The Examiner acknowledges the that the prior art cited is drawn to 2 proteins which are growth factors. However, since:

- 1) both the claimed invention and art cited are drawn to proteins; and
- 2) the art cited teaches modifications of two proteins with different structure and function dramatically affect the biological activity of these proteins

Art Unit: 1817

it is reasonable for a skilled artisan to conclude the biological activity of a protein, such as the MAGE-1 will be dramatically affected contrary to applicants arguments.

Applicants further argue the allowed claims in US Patent No. 5,342,774 support the enablement of the claims of the instant application. Applicants arguments are not persuasive since the scope of claims in the issued patent are not as broad as the claims of the instant application. The scope of the claims must bear a reasonable correlation with the scope of enablement. See in re Fischer, 166 USPQ 19 24 (CCPA 1970). The claimed DNA of the issued patent is drawn to only those nucleic acid molecules which encode for a tumor rejection antigen precursor and hybridize under stringent conditions to the nucleic acid molecule as recited. It is suggested by the Examiner that applicants incorporate the limitation of claim 17 in the claim 8 to obviate the rejection.

The Examiner notes that the claimed MAGE-1 antigen has a molecular weight of about 46 kDa (i.e. claims 8 and 9) and the MAGE-1 antigen disclosed in the specification has a molecular weight of about 43 kDa (see page 19, first full paragraph). Clarification is requested

5. Claims 8-10, 13, and 14 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

#### **NEW GROUNDS OF REJECTION**

6. Claims 8-10, and 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Newly submitted claims 17-20 are rejected for lack of antecedent basis for use of the phrase "claim 1" since said claim was canceled. For examination purposes, the Examiner has read claims 17-20 to depend on claim 8.

Art Unit: 1817

Newly amended claim 8 is rejected for being in an improper Markush format. The Examiner recommends the use of the phrase "...consisting of ..." with the use of the conjunction "and" rather than "or" in listing the species. See MPEP 706.03(Y).

7. Claims 18-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

While the specification has support for claiming an peptide consisting of SEQ ID NOS 2, 3, or 4 (see allowed claim 12) the specification as originally filed provides no support for claiming a MAGE-1 tumor rejection comprising all of these sequences or at least one of these sequences (see newly submitted claims 19 and 20).

Furthermore, while the specification has support for claiming an protein consisting of amino acids 57-219 (see allowed claim 11), the specification as originally filed provides no support for claiming a MAGE-1 tumor rejection comprising said amino acid sequence (see newly submitted claim 18).

8. Claims 11, 12, 15, and 16 are allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

Art Unit: 1817

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Anthony C. Caputa, whose telephone number is (703)-308-3995. The examiner can be reached on Monday-Thursday from 8:30 AM-6:00 PM. The examiner can be reached on alternate Fridays. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703)-308-0196.

Papers related to this application may be submitted to Art Unit 1806 by facsimile transmission. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The Fax number is (703)-305-3014.

Anthony C. Caputa, Ph.D.

September 15 1997



ANTHONY C. CAPUTA  
PRIMARY EXAMINER  
GROUP 1800